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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/190,138	11/12/98	BOSCH H	029315/A109

HM22/0322

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EXAMINER	
MCQUEENEY, P	
ART UNIT	**PAPER NUMBER**
1615	5

DATE MAILED: 03/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/190,138	Applicant(s) BOSCH ET AL.	
	Examiner P. E. McQueeney	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *12 November 1998* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

1. Acknowledgement is made of applicant's response to notice to file missing parts of application filed February 8, 1999 and information disclosure statement filed September 27, 1999.

Claim Rejections - 35 USC § 112

2. Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The independent composition claims (claims 1, 11, 23, 35 and 37) teach several different aerosol compositions. However, the required medicament and its particle size, critical or essential to the practice of the invention, but not included in the claim(s) are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The particle size of a medicament is determined by the site of action of the medicament. "Aerosol size is probably the most important factor determining the site of deposition." Newman, THERAPEUTIC AEROSOLS, p. 203 (1984). However, applicant claims a broad range of medicaments (see claims 2, 14, 25) (claims 35 and 37 don't even have dependent claims specifying medicaments) and a broad particle size range (see claims 3, 15 and 26). Therefore, applicant is not enabled for claims 1-38.

The independent method claims (claims 39, 40 and 42-44) teach a variety of well-known aerosol techniques (claim 39 – water based nebulization) or well-known particle size reducing techniques (claim 40 – spray drying, claims 42 and 43 – milling

and evaporation, claim 44 – freeze drying). Applicant does not disclose any improvement on these known methods. Therefore, applicant is not enabled for claims 39-50.

It appears that applicant is attempting to claim aerosols in which each aerosol droplet comprises drug particle. However, where applicant uses same methodology as known in the art, it is not clear how applicant's invention differs from the prior art.

3. Claims 6-10, 18-22 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant fails to define the term "MMAD" in either the claims or the specification. Furthermore, applicant does not use the term "MMAD" until Example 3 on page 33.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-5, 39 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Wiedmann et al. Wiedmann et al. disclose an aerosol comprising droplets of an

aqueous dispersion of nanoparticles, said nanoparticles comprising insoluble beclomethazone particles having a surface modifier on the surface thereof. Wiedmann et al. disclose claims 1-5 of the present invention in claim 1 and the Example. Wiedmann et al. disclose claim 39 of the present invention in claim 3. Wiedmann et al. disclose claim 46 of the present invention in claims 4 and 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-22, 35-43, 46, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapter 13 of Aerosols in Medicine. Principles, Diagnosis and Therapy (Elsevier Science Publishers, 1993). Folke Moren discloses on page 322,

Section 2.1.1 that for penetration into lower airways, it is generally accepted that the majority of particles should be smaller than 5 μm in diameter. Moren further states that this size can be achieved either by treating the substance in a ball mill or by micronizing in a jet mill. This disclosure fully anticipates applicant's claims 40 and 42 and anticipates claim 43. Claim 11 of the present invention is disclosed in section 2.2.1. Claims 35 and 37 of the present invention are disclosed in section 3.1. Claim 1 of the present invention is disclosed in section 4.1. Claim 39 of the present invention is disclosed in section 4.2.

6. Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapter 13 of Aerosols in Medicine. Principles, Diagnosis and Therapy (Elsevier Science Publishers, 1993) as applied to claims 1-22, 35-43, 46, 47, 49 and 50 above, and further in view of Chapter 84 of Remington's Pharmaceutical Sciences (Mack Publishing Company 1990). Moren does not disclose the lyophilization technique in Chapter 13. Remington's discloses the use of lyophilization on page 1565. "Freeze-drying (lyophilization) is a process of drying in which water is sublimed from the product after it is frozen. The particular advantages of this process are that biologicals and pharmaceuticals which are relatively unstable in aqueous solutions can be processed and filled into dosage containers in the liquid state, taking advantage of the relative ease of processing a liquid. They can be dried without elevated temperatures, thereby eliminating adverse thermal effects, and stored in a dry state in which there are

relatively few stability problems." It would have been obvious to one of ordinary skill in the art to use the technique in Remington's in the teachings of Moren in order to process in an efficient manner biologicals and pharmaceuticals which are relatively unstable in aqueous solutions. The expected result would be aerosols containing a solid that was filled in a liquid form and freeze-dried to the solid in the container.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. E. McQueeney whose telephone number is 703-306-5827. The examiner can normally be reached on weekdays from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

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